Development of Effectiveness Program through the Use of Productivity Metrics

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Abstract *— The Overall Plant Effectiveness Program has the purpose to improve the production capacity and optimize operations performance in an Active Pharmaceutical Ingredient (API) manufacturing plant. It requires a complete analysis of the manufacturing operations including the evaluation of process steps cycle times and identification of factors that impact the operations. A capacity study of the whole operation is necessary to define the capacity available and establish a baseline of the current operations. The implementation of this program serves as a tool to monitor the performance of the manufacturing operations and helps in the long range planning by improving the performance and reducing cycle times. The main goals of the program implementation are the reduction of the current production costs and open capacity for the introduction of new products.*

Key Terms *— Capacity, Effectiveness, Improvement, Performance.*

BACKGROUND

The effectiveness measurements are based on the productivity and the efficiency of the manufacturing operations. The identification of the factors that impact the operations and the implementation of metrics that helps the monitoring of the efficiency should be part of the effectiveness program. The effectiveness measurements in an API Manufacturing Plant are categorized by the following:

- Yield
- Downtime
- Labor Utilization

The total production capacity of an API Manufacturing Plan is determined by the ability of a production area of the manufacturing of a specific volume of products where the uptime is the time used for the manufacturing operation against the total production time available. The long range plan is based on the total production capacity of the manufacturing area using the product cycle time as a limiting factor. The yield measurement represents the conversion of the starting material into the final product. This calculation provides information on the process performance.

Based on Berger (1998) [1] the downtime is the time that the production area is incapable of manufacture or the time used for any other activity than manufacturing such as repairs, preventive maintenance, changeovers and shutdowns. The purpose of the downtime measurement is the identification of the most common problems that affect the manufacturing time. The labor utilization provides information on the performance of the people during the manufacturing operation and their productivity.

Based on Maynard's Industrial Engineering Handbook (1992) [2] the implementation of a successful measurement program is derived from the practicality of the program. Also, to keep a good performance of the system it is very important to provide a realistic measure of the time required to perform a pre-determined operation. The purpose of the implementation of this program is to continuously improve metrics and plant profitability. The conscious of the factors that impact the operations helps the management in the development of plans to timely resolve the problems that affect the operations. The implementation of the program allows the production areas to measure the progress and translate the improvements in savings for the entire operations.

The purpose of the design project is the implementation of a program to evaluate the effectiveness of the manufacturing operations in an API Manufacturing Plant. The performance measurements of each production area allow the development of better long range production plans and utilization of the resources in the operations.

The process step cycle times and the process bottlenecks have to be identified as part of the effectiveness program implementation. Currently, the capacity utilization of the manufacturing areas is not calculated and the shop floor data is not analyzed. A capacity study of the whole operation is necessary to determine the capacity available for the manufacturing of new products.

Currently, the shop floor is the tool used in the manufacturing areas for process monitoring and data gathering. The shop floor is an electronic data base used by the supervisors to record the daily operations in each production area. It is a system used to collect the data related with the manufacturing of a specific product and the respective production area. The production chain is divided per process step identifying the equipment used for each step and the time required for its completion.

The shop floor will be optimized as part of the effectiveness program implementation in order to get accurate data. Currently, the data obtained from the shop floor is not analyzed or evaluated. Nevertheless, the data is gathered by the supervisors to keep monitoring of the production schedule and provide daily status to the management.

The shop floor will be used as a baseline for the Overall Plant Effectiveness calculations as a source of data. Data analysis will be performed of each process step and the optimization of the system is the first step of the program implementation. The results of the calculations and the data analysis have to be reported in a monthly basis.

MANUFACTURING OF CHEMICAL PROCESSES

The chemical industry has been confronted with several external factors that have has a significant impact in the chemical process design and operation as per Meeuse and Grievink [3]. The industry needs to be more flexible to the market changes to keep its competitiveness. A lot of effort is spent today in the industry in the implementation of systems for predictive control and time optimization.

Accurate and repeatable measurements are vital to the successful operation of a chemical process to deliver consistent product while minimizing costs based on Menezes and Graber (1999) [4]. The process control and the monitoring of the operations are the key in the optimization and process improvements in a chemical plant.

The strategy for the implementation of the Plant Effectiveness Program in a Chemical Plant is being developed in one production train considered as a pilot area. The pilot area will perform a time study of the manufacturing operations per process step. The process is divided in eight (8) steps based on the current shop floor and the time required to complete each predetermined operation.

OPERATIONS MANAGEMENT

The concept of operations management is defined by Chase, Aquilano and Jacobs (1998) [5] as the design, operation and improvement of the production systems. The operations management constitutes the basic tool to get the success in every system. The performance of the operation depends on good decisions that have to be taken into one of three (3) broad areas: strategic (long-term) decisions, tactical (intermediate-term) decisions and operational planning and control (short-term) decision.

The strategic decisions impact the effectiveness of the plant in the long-range plan. That means that this kind of decisions must be focus on the customer needs and operations capacity constraints.

The tactical decisions are made taking in consideration the strategic decisions in order to align the long range plans with the intermediate and short term plans. The efficiency of the operations depends on a good coordination and management of the decisions at each level. The operational planning and control issues are related with the schedule of the week and what jobs have priorities in order to comply with customer demands.

Based on Chase, Aquilano and Jacobs (1998) [5] the basics of the operations management are the production systems which consist of people, plants, parts, processes, and planning and control systems. People are the direct and indirect workforce. Plants include factories and/or the place where the manufacturing is performed. The materials are called parts and the processes include the equipment and the steps by which production is accomplished. All the procedures and the tools used to manage the system are called planning and control.

PRODUCTIVITY METRICS

Productivity is defined by Chase, Aquilano and Jacobs (1998) [5] as a common measure of how well a country, industry, or business unit is using its resources. In summary, productivity is defined as ration between outputs and inputs (Productivity = Output / Input). To increase productivity, this ratio must be as large as practical. The productivity is a measure that can be used to compare similar operations or to evaluate an operation over time within the same operation. Frequently, it is necessary to create productivity measures related to some particular factor. This process provides the tools of shifting the level of the analysis and accomplishes with the improvement needs.

The continuous improvement is the key or the main reason for the implementation of the productivity metrics in the industry today. Since the continuous improvement seeks better processes and quality, this is a challenge for any industry to keep competitive in the market. Often the product and process improvements require an investment but at the same time a cost reduction on a long range plan.

Based on Montgomery (1997) [6] the statistical process control is a powerful collection of problem-solving tools useful in achieving process stability and improving capability through the reduction of variability. These tools can be applied to any process.

Based on Montgomery (1997) [6] the control charts are a proven technique for improving productivity. A successful control chart program will reduce scrap and rework, which are the primary productivity killers in any operation. That means that it is possible to increase the productivity and decrease the costs with an effective process control system.

DATA ANALYSIS CONCEPTS AND REPORTING TECHNIQUES

The statistical process control involves testing a random sample of output from a process to determine whether the process is producing items within a pre-selected range as described by Chase, Aquilano and Jacobs (1998) [5]. When an output results is out of the range, it is a signal that the production process must be adjusted to take it back to the acceptable range.

Process control is regards the monitoring of the quality while the product or service is being produced as per Chase, Aquilano and Jacobs (1998) [5]. The purpose of the process control is obtained information on the process and/or recognizes problems in a timely manner to avoid producing items out of the pre-determined specifications. In addition, it is the objective of the process control to obtain the necessary information to establish corrective and preventive plans to increase the productivity and continuous improve the operations.

The process control with variable measurements using X and R charts. The process control charts are developed to determine the acceptability or rejection of the process based on the measurements obtained from the process. The values are used to create or modify control charts and see whether or not they fall within the acceptable limits.

The major issues to address in creating a control chart are the size of samples, number of samples, frequency of sampling and control limits. The size of samples is defined by the length of time related with the process changes and the cost to take it. The number of samples is defined once the chart has been set up and it is suggest approximately 25 samples be taken. The cost of the sampling determined the frequency and the confidence gained during the sampling process can adjust it. The standard practice in statistical process control for variables is to set control limits three (3) standard deviations above the mean and three (3) standard deviations below. This means that 99.7 percent of the sample means are expected to fall within these control limits. If one (1) sample mean falls outside the wide band, it shows that the process is out of control.

PROCESS DEFINITION

The process was divided in eight (8) steps based on the current shop floor and pre-determined operations. The steps identified in the production train are described below.

Step 1: Reaction Completion

The starting material is dissolved in slurry with a solvent and a reactant at ambient temperature in tank #1. The reaction mixture is heated. Then, the reaction mixture is maintained at the temperature specified under continuous agitation until the reaction is completed. An in process test method is performed to determine the reaction completion. After the reactor is cooled, the reaction mixture is added slowly to a basic solution in order to quench the reaction mixture in tank #2. The reaction mixture final conditions are verified through an in process check.

Step 2: Phase Separation

After the quench is completed, another solvent is added to tank #2. The pH is adjusted using an acid aqueous solution. Then, the phases are separated, and the aqueous phase is solvent extracted with a second portion of the solvent to reduce product losses in tank #2. The organic phases are combined in tank #3. Then, the phases are separated and water cut is performed in tank #3. An in process test method is used to determine product content in the aqueous phase contained in tank #2. If the in process test method shows product in the aqueous phase, one or more solvent extractions have to be performed to recover the product.

Step 3: Distillation

The pH in the aqueous phase is adjusted with a basic solution in tank #2. Then, the aqueous phase is discarded to the chemical sewer. The product solution is transferred from tank #3 to tank #4 and vacuum distilled until a specific volume is reached. The solvent distillates are received in tank #5. These distillates are washed with water to be used in the next batch extraction. Then, a re-distillation of a mixture of two solvent is performed in tank #4.

Step 4: Crude Crystallization and Filtration

Distillation of a mixture of two (2) solvents is performed until the pre-determined water content is reached in tank #6. The additions of these solvents followed by a distillation are repeated until the specific water content is reached. The solvents mixture is added for the crude crystallization in tank #6. The pH is adjusted with an acid aqueous solution. The crude slurry is agitated for a minimum of one (1) hour at a specified temperature. The product is filtered and washed with a solvents mixture in filter #1.

Step 5: Dry and Dissolve

The product is dried with nitrogen at a specified temperature, which is monitored for a period of 6 – 12 hours in filter #1. When the drying period is completed the product is dissolved in hot water at a specified temperature. Once dissolved, the solution is transferred to tank #7.

Step 6: Water Distillation

The product solution is concentrated by distilling some of the water under vacuum until specified volume is obtained in tank #7. A solvent is added to the concentrated solution, and the mixture is heated. Then, the solution is transferred to tank #8 into more solvent for final crystallization. The final solution is seeded with authentic crystals.

Step 7: Final Crystallization and Filtration

After the total amount of seed is added, the solution is rapidly cooled in tank #8. Then, the cooling rate is decreased until the desired temperature is reached. The crystals are maintained at the specific temperature for a minimum of two (2) hours. The product is filtered and washed with a solvent in filter #2.

Step 8: Dry, Pack and Mill

The product is dried with nitrogen until the specified water content is reached in filter #2. The minimum time of drying must be a minimum of 12 hours. The final product is deagglomerated in a Milling Machine and then packed in fiber drums.

DATA COLLECTION

The manufacturing area performed a time study during one (1) month of its operations, which run 24 hours per day and 7 days a week. The process was divided in eight (8) steps based on the current shop floor and following manufacturing instructions that can facilitate the data collection. The time required to complete each pre-defined operation was measured and documented. The purpose of this information is to evaluate the process cycle time and, improve and monitor the capacity planning system. The data was collected by the manufacturing supervisors directly on the floor, record in an electronic tool developed for this study and compared against the standard time used for the development of the production schedule. The standard time is a theoretical time calculated based on process definition and pilot plan execution.

The data collected during the time study was used to identify deviations on the cycle time calculation, develop improvement opportunities and increase the productivity of the manufacturing area. The data evaluation included standard deviation, production rate and efficiency calculations.

PRODUCTION RATE CALCULATIONS

The production rates were calculated using the lots started per product per month. This data provided information on the current production capacity at the plant and its capacity to add more products to the areas, which are able to manufacture multiple products.

Example:

$$\text{Production Rate in a month} = (\text{Lots started/month})*(7\ \text{days/week})/(30\ \text{days/month}) = (22*7)/30 = 5.13\ \text{lots/week} \quad (1)$$

Production rate is calculated per product campaign since this is a dynamic multiproduct area. The cycle time was calculated per product using the total lots manufacture per campaign divided by the time period. The production time includes the cleaning associated with the particular product. In addition, the production rate calculation was performed against each production train and the ten (10) products validation at the manufacturing area.

EFFICIENCY CALCULATIONS

The efficiency of the area is calculated based on the lots started during the month and compared with the theoretical information used for capacity planning calculations. The values greater than 100% means that the production rate in a particular rate in a particular area is faster than stated in the capacity tool. Some variables can impact the efficiency results such as delays in the cleaning process and planned downtimes.

Example:

$$\text{Efficiency of Area \#1} = (\text{Lots/week calculated}) / \text{Production Rate} = (5.13) / (4.75) * 100 = 108\% \quad (2)$$

The results of the time study performed at the manufacturing area are presented in the Table 1: Production Cycle Time Study. This represents one (1) month of data collection where 22 lots were completed at the manufacturing area.

Table 1
Production Cycle Time Study

Lot #	Step 1 (hrs)	Step 2 (hrs)	Step 3 (hrs)	Step 4 (hrs)	Step 5 (hrs)	Step 6 (hrs)	Step 7 (hrs)	Step 8 (hrs)	Total (days)
1	30	27	26	25	15	16	19	14	7.2
2	31	27	34	11	15	24	25	22	7.9
3	30	32	24	27	15	24	13	12	7.4
4	30	26	34	29	13	19	20	22	8.1
5	32	27	34	17	15	10	25	10	7.1
6	30	19	30	29	15	12	17	22	7.2
7	24	19	38	20	7	36	21	22	7.8
8	18	27	34	25	24	33	10	14	7.7
9	16	27	29	33	15	16	17	22	7.3
10	24	21	34	25	18	16	6	15	6.6
11	30	27	16	44	14	16	15	22	7.7
12	30	18	41	25	14	16	17	15	7.3
13	24	19	34	33	20	16	15	12	7.2
14	28	23	42	28	7	16	25	12	7.6
15	33	27	34	25	15	16	13	12	7.3
16	30	27	36	25	15	30	13	12	7.8
17	30	27	34	25	15	12	20	20	7.6
18	30	27	34	19	14	21	12	18	7.3
19	30	23	30	40	22	16	26	15	8.4
20	30	15	51	37	14	18	14	22	8.4
21	28	27	40	34	15	24	25	22	9.0
22	35	19	42	28	15	24	25	22	8.7

In addition, table 2 summarizes the data evaluation results.

Table 2
Data Evaluation Results

STEP	STD TIME	AVERAGE	MEDIAN	STD DEV	MIN VALUE	MAX VALUE	POTENTIAL TIME
1	30	28	30	4.52	16	35	24
2	27	24	27	4.33	15	32	19
3	34	34	34	7.08	16	51	30
4	25	28	26	7.52	11	44	25
5	15	15	14	3.77	7	24	14
6	24	20	16	6.77	10	36	16
7	25	18	17	5.69	6	26	13
8	22	17	17	4.54	10	22	12

This data represents one (1) month of production and it shows the potential of reducing the cycle time and increases the productivity of the manufacturing area. Based on the information gathered during the time study, the step 3 (distillation) is the process bottleneck since takes more time than the other steps. One of the most important factors that impact the time of the process steps are the equipment failures and maintenance works. These factors are unplanned downtimes added to the time calculated per process step. The majority of the high peaks shown per step can be related with equipment downtimes as long as process matters. This production data shows the potential of reducing the cycle time of the manufacturing area. The production shop floor step times would be improved as shown in Table 2 based on the best values obtained from the data collected. The total production time may be reduced from 202 to 153 hours, which represents a potential reduction of approximately 24%.

Another month of data was collected in order to compare and evaluate the potential reduction on cycle time. It was observed a reduction in time from 202 to 178 hours, which is still below the potential reduction. However, improvement on the standard deviation was observed and the reduction of approximately 12%.

The information gathered will be useful to adjust the cycle time and production rates. As part of this analysis, the frequency of the incidents that cause downtime and process delays were identified in order to develop action plans. One of the opportunities for improvement identified is the spare parts inventory. Some of the incidents were related with parts required for replacement, maintenance and/or repair work, which were not available.

In addition, the cycle times were calculated based on the information obtained from the shop floor capacity modeling tool. The production rates were calculated using the lots started per product per month.

A summary of the production rates for a four (4) months period is shown in Table 3. The table includes the actual production rates based on the total of lots started per month and the production rates estimated for the capacity planning calculations. This data is used to calculate the efficiency per production area.

Table 3
Production Capacity Summary

Product	Area #1	Area #2	Lots per week			
	Production Rate (Lots/Week)	Production Rate (Lots/Week)	Month 1	Month 2	Month 3	Month 4
A	1.80	-	1.58	1.50	1.35	-
B	4.75	-	4.29	4.50	4.52	5.13
C	1.00	-	-	-	-	0.93
D	1.90	1.00	0.68	-	-	-
E	1.30	0.70	-	0.79	-	-
F	1.00	0.70	-	-	1.45	0.70
G	0.70	0.50	-	-	-	-
H	1.50	-	0.90	0.75	1.13	1.40
I	3.00	-	0.90	1.25	1.58	1.40
J	3.00	-	-	-	-	-

The efficiency of the area is calculated based on the lots started during the month and compared with the theoretical information used for capacity planning calculations. The values greater than 100% means that the production rate in a particular rate in a particular area is faster than stated in the capacity tool. Some variables can impact the efficiency results such as delays in the cleaning process and planned downtimes.

RECOMMENDATIONS

Based on the productivity evaluation, one of the opportunities for improvement identified is the spare parts inventory. Some of the incidents were related with parts required for replacement, maintenance and/or repair work, which were not available. It is recommended to revise the spare parts inventory with the Maintenance Department in order to avoid any potential downtime.

Other recommendations are to add specific steps to the Master Record to optimize the time measurements. Improve the data collection tool to include details on the delays identified during the process. In addition, better tracking of the cleaning campaigns is required in order to improve the downtime cause by this process.

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